



**ASSESSMENT
OF THE
CONTRACEPTIVE TECHNOLOGY RESEARCH PROJECT
AT
FAMILY HEALTH INTERNATIONAL
1995–2005**

EXECUTIVE SUMMARY

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ACRONYMS AND ABBREVIATIONS

BASS	Behavioral and Social Sciences Research Group (FHI)
BCC	Behavior change communication
CA	Cooperating agency
CBR	Center for Biomedical Research (the Population Council)
CDC	Centers for Disease Control and Prevention
CEO	Chief executive officer
CICCR	Consortium for Industrial Collaboration in Contraceptive Research (CONRAD)
CONRAD	Contraceptive Research and Development Program
CRD	Clinical Research Department (FHI)
CTO	Cognizant technical officer (USAID)
CTR	Contraceptive Technology Research project (FHI)
CTR/Nairobi	CTR East and Southern Africa Regional Office (FHI)
ECPG	Essential Care Practice Guidelines
ESA	East and Southern Africa
FDA	U.S. Food and Drug Administration (U.S. Department of Health and Human Services)
FHI	Family Health International
FITS	Field Information and Training Services Department (FHI)
FP	Family planning
GH/HIDN	Bureau for Global Health, Office of Health, Infectious Diseases and Nutrition
GH/OHA	Bureau for Global Health, Office of HIV/AIDS
GH/PRH	Bureau for Global Health, Office of Population and Reproductive Health
GH/PRH/CSL	Bureau for Global Health, Office of Population and Reproductive Health, Commodities Security and Logistics Division
GH/PRH/RTU	Bureau for Global Health, Office of Population and Reproductive Health, Research, Training and Utilization Division
GH/PRH/SDI	Bureau for Global Health, Office of Population and Reproductive Health, Service Delivery Improvement Division
GMP	Global Microbicide Project (CONRAD)
GRIPP	Getting Research into Policy and Practice Initiative
GTZ	German Technical Cooperation
HIV/AIDS	Human immunodeficiency virus/acquired immune deficiency syndrome
HPTN	HIV Prevention Trials Network
HSR	Health Services Research Division (FHI)
IBP	Implementing Best Practices Initiative
ICPD	International Conference on Population and Development (Cairo)
IFH	Institute for Family Health (FHI)
IMPACT	Implementing AIDS Prevention and Care project (FHI)
IPM	International Partnership for Microbicides
IR	Intermediate Result
IUD	Intrauterine device
MAQ	Maximizing Access and Quality Initiative
MOH	Ministry of Health
MTCT	Mother-to-child transmission
NDA	New drug application
NGO	Nongovernmental organization
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
OR	Operations research
PATH	Program for Appropriate Technology in Health
PHSC	Protection of Human Subjects Committee (FHI)

PMA	Premarket approval application
PMTCT	Prevention of mother-to-child transmission
POPTECH	Population Technical Assistance Project
PQC	Product Quality and Compliance Group (FHI)
QC/QA	Quality control/quality assurance
QSD	Quantitative Sciences Department (FHI)
R&D	Research and development
RH	Reproductive health
RHD	Reproductive Health Programs Department (FHI)
RtoP	Research to Practice Initiative
STI	Sexually transmitted infection
TAC	Technical advisory committee
TRIP	Turning Research into Practice Initiative
USAID	U. S. Agency for International Development
VCT	Voluntary counseling and testing
WHO	World Health Organization
WHO/RHR	World Health Organization, Department of Reproductive Health and Research

EXECUTIVE SUMMARY

BACKGROUND

The current cooperative agreement between the U. S. Agency for International Development (USAID) and Family Health International (FHI) was awarded in 1995 and ends August 30, 2005. The Contraceptive Technology Research (CTR) project is intended to support research and development (R&D) of new or improved contraceptive and microbicidal products that are effective, safe, acceptable, and affordable, and that can be provided through family planning (FP), HIV prevention, and other reproductive health (RH) programs in developing countries. In part because of USAID's continuous, consistent, and long-term investment in the CTR project over nearly three decades, FHI has become the leading public sector biomedical and biotechnical research organization.

METHODOLOGY

The purpose of this assessment was to

- assess the performance of the CTR project relative to the goals and objectives of the cooperative agreement,
- assess the results of CTR's research findings and capacity-building activities on FP and RH programs worldwide, and
- provide guidance to USAID for the design of a follow-on project.

A team of four individuals conducted the assessment over a 6-week period from mid-September through October 2003. Sources of information included

- background documents, including a comprehensive self-assessment prepared by FHI;
- interviews with over 70 individuals from 23 different organizations;
- discussions with staff from USAID/Washington and five Missions;
- meeting with FHI/CTR staff in North Carolina for 3 days; and
- a week-long visit to Kenya to meet with CTR/Nairobi East and Southern Africa (ESA) Regional Office staff and to make field visits to ongoing research studies.

KEY FINDINGS AND RECOMMENDATIONS

Strengths

“FHI is uniquely positioned to do a lot of good for the world.”

CTR received high marks for its clinical R&D capacity. Respondents also complimented CTR staff members for being collaborative, characterizing them as “highly skilled,” “forward thinking,” “flexible,” and “very technically competent professionals who are passionate about the work they do.” Many individuals praised CTR for providing leadership in the integration of FP and HIV/AIDS and male and female condom use as well as for advocating an RH focus in the face of vertical HIV/AIDS funding.

Weaknesses

“They need to be more intellectually proactive and strategic rather than just responsive.”

Several respondents commented that CTR has largely followed the direction of USAID/Washington, that it is too headquarters based, and that “they need to make more strategic decisions on which studies to undertake.” Respondents also raised several management issues as weaknesses, including the need to decentralize decision-making. Finally, although many respondents spoke positively about FHI’s efforts to disseminate research findings, most acknowledged that taking research to practice is a challenge for all research organizations.

Research Quality and Impact

Since 1971, CTR has had an integral role in helping USAID achieve its contraceptive research goals and objectives. In the past eight years, CTR has either met or exceeded all of the output targets set as the evaluation criteria in the cooperative agreement. CTR completed 137 studies to understand and improve contraceptive method use (50 were projected), conducted 6 phase 2/3 safety and efficacy clinical trials (3 were projected), and introduced new methods into 11 countries (5 were projected). CTR should be commended for this success. This measurement, however, stops short of showing impact in terms of programmatic change and putting research into practice. **Addressing this gap should be encouraged and measured in the follow-on project.**¹

Contraceptive and Microbicide Research

In the current CTR agreement, 150 studies were conducted to evaluate contraceptive safety and efficacy, assess contraceptive risks and benefits, and improve contraceptive method use. These studies led to the approval of five contraceptive products by the U. S. Food and Drug Administration (FDA) (the Filshie Clip, eZon condom, Tactylon condoms, FemCap, and the Lea’s contraceptive device). Other studies led USAID to discontinue providing vaginal foaming tablets and to cease recommending use of nonoxynol-9 as a spermicide. In addition to the six phase 2/3 safety and efficacy studies with condoms, diaphragms, spermicides, vaginal gels, and vasectomy technologies, CTR has three phase 2/3 studies with microbicides in progress.

Behavioral, Economic, and Programmatic Research

CTR undertakes both health services research and behavioral and social sciences research. A significant proportion of ongoing CTR studies (39 percent) are taking place in FHI’s East and Southern Africa (ESA) Region, with most of the studies being

¹ Throughout the report, recommendations by the assessment team are shown in boldface type.

conducted in Kenya. CTR's research in Kenya has led to a number of changes in policies and programs in the country. For example, a study on menstruation requirements as a barrier to contraceptive access led to the development of a checklist to rule out pregnancy and thereby increased access to contraception for nonmenstruating women. ***The important question now is how CTR can achieve a similar impact in countries where it does not have the same level of field staff or Mission support.***

Research to Practice Initiative

With the creation of the Research to Practice (RtoP) Initiative in 2001, CTR introduced a more formalized approach to turning research into practice and has begun to change the organizational culture of FHI to institutionalize a research to practice approach. The RtoP Initiative has focused primarily on identifying key priorities among existing CTR findings to bring into practice. Using three criteria—a solid body of evidence, public health impact, and likelihood of use—staff identified four key priorities: intrauterine devices (IUDs), checklists, vasectomy, and nonoxynol-9 spermicides. ***In the future, it would be useful to explicitly apply a similar but modified set of criteria when choosing to undertake studies.*** One of the first major activities of the RtoP Initiative has been to reintroduce the IUD in Kenya. ***The lessons from this experience should be used to help inform future research to practice efforts.*** Field presence greatly enhances turning research into practice because “locally based staff have the best understanding of issues.” Therefore, **CTR should examine ways to take advantage of the global presence of FHI's Implementing AIDS Prevention and Care (IMPACT) Project**, which has field offices in more than 40 countries.

Product Quality and Compliance Group

The Product Quality and Compliance Group (PQC) is one of a few laboratories in the world capable of performing high-quality condom testing. Over the years, PQC has provided technical assistance in the areas of quality assurance, product evaluation, standards development, training on standards, and enhancement of laboratory capacities. This is reflected in the continued requirement for PQC to retest 100 percent of all lots.

Management and Financial Issues

In recent years, the magnitude and rate of growth at FHI accelerated to the point that major restructuring was required. Over the past two years, FHI has been split into two parallel institutes, HIV/AIDS and Family Health; each is headed by a president and a chief operating officer (senior vice president for operations, a new position created to relieve each president of many day-to-day management and administrative duties). Because of CTR's increasing involvement in HIV/AIDS research and programs, **these two institutes should work more closely in developing their work plans to take advantage of potential synergies.**

Portfolio Assessment

Contraceptive and Microbicide Research Relative to the Contraceptive Research and Development Program (CONRAD) and the Population Council

The contraceptive and microbicide programs at CONRAD, the Population Council (the Center for Biomedical Research [CBR]), and FHI (CTR), which are supported by USAID cooperative agreements, are supplementary and complementary. USAID's support of these three organizations provides a greater opportunity for success in USAID's mission to develop new and improved contraceptives and microbicides. In addition, continuing support of these agencies is more important now than ever before because these two areas of research—contraceptives and microbicides—have become critically dependent on public sector support due to the exodus or lack of interest of industry. **USAID should continue to support CTR, CONRAD, and the Population Council's CBR in their critical R&D efforts to provide the public with new or improved contraceptives and microbicides.**

Program Research Relative to FRONTIERS and Other Operations Research

Although multiple USAID-funded organizations engage in operations research (OR), the two primary agencies involved in OR are FHI, through its Health Services Research Group (HSR), and the Population Council, through FRONTIERS and Horizons. CTR conducts programmatic research on contraceptive technology, which is driven by family planning methods. For the FRONTIERS project, the focus is more on systems; its OR generally “does not start with a method, but looks at the situation of program managers.” In addition to the fact that there is little overlap between the CTR and FRONTIERS portfolios, there are also many benefits to having multiple organizations involved in OR, including increased innovation and creativity. **USAID should continue to support the OR programs of both CTR and FRONTIERS.**

FUTURE DIRECTIONS

The current CTR agreement began in August 1995, one year after the pivotal International Conference on Population and Development (ICPD) in Cairo. ICPD helped to expand the perspective of the population and FP field to look more broadly at RH. Now, almost 10 years later, FP is at risk of being lost due to the dominance of HIV/AIDS in public thinking and donor funding. With 230 million women in the world lacking information on and access to a full range of contraceptive methods, it is essential not to lose focus on the unfinished FP agenda. Towards that end,

- **USAID should ensure continued high levels of funding for FP and**
- **CTR should ensure a continuing focus on improving FP programs.**

Proposed Configuration

Initially focused on carrying out clinical trials of contraceptive methods, CTR has grown to embrace behavioral, programmatic, and economic research and to create methodologies and high standards for how this research should be conducted in the developing world. CTR also ensures the quality of condoms and other family planning methods through PQC. Respondents were unanimous in their support for maintaining

CTR’s broad capabilities in a future project: “I think this [CTR] has worked—USAID needs to think carefully before they dissect it.” **The follow-on CTR agreement should maintain the same components and capabilities—clinical, behavioral, economic, and programmatic research; product quality testing; and the research to practice approach—found in the present project.**

Contraceptive and Microbicide Research

Because the contraceptive pipeline is not very robust, the focus of a follow-on project should be to make existing methods more attractive and widely used. While it is important to remain prepared to undertake phase 2 and 3 evaluations of any contraceptive candidates that emerge from CONRAD’s pipeline, **CTR needs to remain focused on research to extend the safety and acceptance of existing contraceptives and to improve their continuation rates.**

There is an urgent public health need to develop a woman-controlled vaginal microbicide to reduce the transmission of HIV/AIDS during intercourse. There is concern, however, regarding the large-scale study design of the proposed (and soon to be ongoing) phase 2 and 3 clinical trials of up to eight compounds. The failure to perform phase 2 studies to assess efficacy using a small number of subjects is a major constraint to the selection and/or establishing the priority of the microbicide candidates as well as dosage and treatment regimens. **USAID and CTR should continue to press for simpler, less expensive study designs (e.g., two-arm, fewer subjects) and take the lead in working with collaborators to implement a strategy for selecting and setting priorities for those microbicides in various pipelines.** Despite these concerns, however, **CTR should continue as quickly as possible the assessment of Savvy and cellulose acetate as well as any other microbicides that CONRAD may offer for clinical testing.** The conservative, streamlined clinical trial design proposed by CTR should be used, while remaining vigilant for potential improvements.

Product Quality and Compliance Group

Although it would be possible to establish a freestanding organization with the same or similar mission as PQC, both CTR and PQC benefit from their integrated association. Separation of PQC from CTR would provide neither economies of nor efficiencies in their operations. **PQC should remain a component of FHI with an expanded scope of work and its mission should be included as an integral part of CTR in the follow-on project.**

Behavioral, Economic, and Programmatic Research

The two key priority areas for future behavioral, economic, and programmatic research are

- ***increasing the use and continuation rates of existing FP methods.*** As one respondent asked, “Have we gotten all the mileage out of what’s out there already?”
- ***understanding the integration and interaction of FP and HIV/AIDS.*** This includes exploring contraception/HIV health considerations and improving the

integration of FP and HIV/AIDS, for example, through voluntary counseling and testing (VCT) and prevention of mother-to-child transmission (PMTCT) services.

Capacity Building

Having a sufficient number of qualified researchers and clinical trial sites is critical over the next 10–15 years (at a minimum) for winning the war against AIDS, tuberculosis, and malaria, and to continuing contraceptive research. **CTR should continue to build on its comparative advantage by focusing on increasing the number of developing country researchers and local staff qualified to design, implement, analyze, and use the results of contraceptive and microbicide research, and by identifying and developing clinical trial sites.**

Research to Practice

Although in its infancy, the RtoP Initiative is a necessary addition to CTR’s portfolio. ***CTR should continue an RtoP Initiative, and a discrete amount of core funds should be set aside for this activity.*** In addition, several respondents stated that “this type of initiative is critical but should be bureauwide and involve all the cooperating agencies (CAs).” **USAID should consider creating a new procurement that would expressly facilitate the use of best practices.**

Monitoring and Evaluation

The current CTR agreement has focused on output measurements, such as number of studies conducted, number of peer-reviewed publications, and number of workshops. With the current focus and attention placed on turning research into practice, it is important that the follow-on project contain more emphasis than the current project on outcome and effectiveness measures. This will help to ensure that the next CTR agreement is guided by the principles of turning research into practice. In addition, documenting, measuring, and analyzing the research and use process will provide valuable insights and lessons on how better to translate research into practice and impact. For the next project, **staff from FHI, the Population Council, and USAID’s Research and Technology Utilization (RTU) and Service Delivery Improvement (SDI) divisions should develop a core set of indicators for measuring both the determinants and extent of use of research findings.**

Funding Mechanisms

The follow-on project should continue as a cooperative agreement, allowing flexibility in interpretation and implementation with substantial involvement by USAID/Washington. **The present level of core funding should be maintained or increased for the follow-on project.** By all accounts, it may take more than a decade for the microbicide research currently in the pipeline (even if rationalized to a few of the best leads) to result in highly effective products. Dismantling the existing research infrastructure in the current CTR—and thus derailing further development and introduction of these products—would set the public health agenda back by a decade. **USAID should continue its support of current CTR contraceptive and microbicide research by awarding a 10-year,**

noncompetitively bid cooperative agreement to FHI when the present project ends in 2005.

In summary, by benefiting from nearly three decades of CTR funding, FHI has become one of only a few organizations that has the breadth and expertise to conduct high-quality RH research in the developing world. Many of those interviewed expressed support for continuing to infuse this RH capacity and perspective into HIV/AIDS programs and research. In order to continue to promote this approach, **the follow-on CTR agreement should broaden its research mandate to allow for funding and research requests from the three offices in USAID's Bureau for Global Health—Population and Reproductive Health (GH/PRH), HIV/AIDS (GH/OHA), and Health, Infectious Diseases and Nutrition (GH/HIDN).** Such a funding mechanism would allow CTR to bring its contraceptive research (clinical, behavioral, programmatic, and economic) and RH focus to bear on the current major public health problems and to promote integrated solutions to complex problems.



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